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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,750	09/05/2003	Johnson E. Goode	P0011367.00	9063

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
11/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,750	GOODE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-40* is/are allowed.

6)☒ Claim(s) *1-12,16,18,22 and 41* is/are rejected.

7)☒ Claim(s) *13-15, 17, and 19-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 10, 11, 16, 22, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Accisano, III (U.S. Patent No. 5,571,085). Accisano, III discloses a medical therapy delivery device having a shaft formed by an outer layer (44) with a first non-deflectable portion (shown at 44 in Figure 1) and a second portion (shown at 54 and 64 in Figure 3). As shown in Figure 3, a deflectable tip extends distally from the second portion and has a tapered portion and a tip lumen (shown at 55 in Figure 4). The device also includes a manipulator wire (47) that extends through the shaft and a thru lumen tubing (46) having a thru lumen. In Figure 4B, the outer layer of the shaft forms a single shaft lumen having a first lumen portion (shown at 50 in Figure 4B) positioned about the thru lumen tubing and a second lumen portion (shown below the first lumen portion in Figure 4B) having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. The second lumen portion is offset from and in fluid communication with the first lumen portion. As to claim 2, the outer layer is formed of polyether block amide or PEBA (line 66 of column 7 to line 2 of column 8). As to claim 10, see lines 39-41 of column 9. As to claim 11, as shown in Figures 4, 4A, and 4B, an anchoring device or band (60) is

positioned along a distal end of the second portion and is fixedly engaged with the manipulator wire (47). Also shown is the manipulator wire (40) that extends through the transition lumen of the transition tubing (50). As to claim 16, see lines 51-65 of column 11). As to claim 22, the first lumen portion is generally semi-circular in shape and the second lumen portion is generally rectangular in shape. As to claim 41, the thru lumen tubing (46) forms a single lumen.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accisano, III in view of Hayzelden (U.S. Patent Application Publication No. 2003/0050598). Accisano, III discloses the invention substantially as claimed. Even though Accisano, III teaches in lines 6-20 of column 8 and in line 64 of column 8 to line 10 of column 9 that the outer layer (44) contains a steel braiding (58) to provide rigidity and strength to the shaft, Accisano, III is silent on the specifics of the outer layer including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figures 1-3, Hayzelden shows the outer layer (42) of a medical device having a first portion (12) made of a high durometer (such as 63D) polyether

block amide with a stainless steel braiding (44) and a second non-braided portion (14) and teach that the braiding provides reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Accisano, III with a high durometer (such as 63D) polyether block amide with a stainless steel braiding as taught by Hayzelden as both Accisano, III and Hayzelden disclose devices having a deflectable second portion and Hayzelden teaches that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the first portion having a durometer reading of 72D and the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Hayzelden teaches that the first portion (12) would have a higher durometer reading than the second portion (14) and that the second portion (14) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer readings of the first portion and the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a length of approximately one inch in claim 18, the parameters of length is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Accisano, III in view of Hobbs et al (U.S. Patent No. 5,584,821). Accisano, III discloses the

invention substantially as claimed. However, Accisano, III is silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material. Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deflectable tip of Accisano, III from a radio opaque and echo-genic polymer material such as a polyether block amide material loaded with tungsten as taught by Hobbs et al as both Accisano, III and Hobbs et al teach advancing a medical device in narrow vessels or cavities and Hobbs et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced in the body.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Accisano, III in view of Hobbs et al as applied to claim 4 above, and further in view of Kousai et al (U.S. Patent No. 4,778,455). Accisano, III and Hobbs et al disclose the invention substantially as claimed. Even though Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten, Hobbs et al are silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material such as tungsten carbide and having a durometer of 35D. Kousai et al disclose a medical device having a tip (1) made of a polymer material loaded with tungsten carbide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the tungsten of Hobbs et al with tungsten carbide as taught by Kousai et al as both Hobbs et al and Kousai et al teach advancing a medical device in narrow vessels or cavities and Kousai et al teach that it is

well known to use tungsten or tungsten carbide in the distal tip to allow the distal end of the medical device to be seen by the user as it is advanced in the body. As to the limitation of the PEBA material having a durometer reading of 35D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

7. Claims 6-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accisano, III. Accisano, III discloses that the tip includes a distal opening and, in Figure 4, the distance between the outer wall and inner wall gradually decreases between the proximal end and the distal end of the tapered portion. Accisano, III also discloses the thru lumen being formed by a PEBA material (lines 11-27 of column 9). However, Accisano, III does not disclose the thicknesses of the walls of the deflectable tip or the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results. As to the limitation of the thru lumen tubing being formed by a PEBA material having a durometer reading of 72D in claim 7, the parameter of the durometer reading of the thru lumen tubing is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in of a polyimide material having a durometer reading of 86D in claim 12, Accisano, III does disclose the transition tubing formed of a polyimide material (lines 54-66 of column 9) and the parameter of the durometer reading of the transition tubing is deemed a matter of design choice, well

within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Allowable Subject Matter

8. Claims 13-15, 17, and 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 23-40 are allowed.

Response to Arguments

10. Applicant's arguments filed July 13, 2009 have been fully considered but they are not persuasive. As to Applicant's arguments on page 16 regarding the manipulator wire, Accisano, III disclose that the manipulator wire (47) is a straight, generally cylindrical elongated wire (see lines 28-34 of column 9). Applicant's arguments on page 17 regarding the "pull cables" are unclear as neither the pull cables or nor the items 48 and 52 have been used in the rejection. As to Applicant's arguments on page 17 with respect to the "bonding sleeve", the bonding sleeve (50) itself has not been used in the rejection. As detailed above, reference numeral 50 has been used to show the location of the first lumen portion of the single shaft lumen in Figure 4B. The outer layer (44) forms a single shaft lumen and this single shaft lumen has a first lumen portion which is the portion of the single shaft lumen shown at 50 in Figure 4B and which is positioned about the thru lumen tubing (46). Therefore, the bonding sleeve (50) is not being used

as a shaft lumen but is being used to shown the location of the first lumen portion. The wall of the bonding sleeve (50) is being used for the first side wall, the second side wall, and the bottom side wall as the portion of the single shaft lumen which has been established as a second lumen portion contains the first side wall, the second side wall, and the bottom side wall of the bonding sleeve (50). It should be noted that no specific structure has been claimed for the first lumen portion of the single shaft lumen. Therefore, a single shaft lumen having a first lumen portion positioned about the thru lumen tubing has been interpreted as a first portion of the lumen or a first lumen portion which is located or positioned about the thru lumen tubing. Similarly, the second lumen portion is being interpreted as a second portion of the lumen or a second lumen portion which is offset from and in fluid communication with the first lumen portion and this portion of the single shaft lumen (i.e., the second lumen portion) has a first side wall, a second side wall, and a bottom side wall as claimed.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ockuly et al (U.S. Patent No. 5,395,328) disclose positioning a manipulator wire within an X-shaped lumen such that the wire remains generally co-axial within the catheter body (lines 16-35 of column 4).

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
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